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Mallinckrodt Inc. and Mallinckrodt LLC

IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF NEW JERSEY

MALLINCKRODT INC. and MALLINCKRODT LLC, Plaintiffs, v. WATSON LABORATORIES, INC.-FLORIDA, WATSON PHARMA, INC. and WATSON PHARMACEUTICALS, INC., Defendants.	)	Civil Action No. _____

COMPLAINT FOR PATENT INFRINGEMENT

Mallinckrodt Inc. and Mallinkcrodt LLC (collectively, "Mallinckrodt"), for their Complaint against Watson Laboratories, Inc.-Florida ("Watson Laboratories"), Watson Pharma, Inc. ("Watson Pharma") and Watson Pharmaceuticals, Inc. ("Watson Pharmaceuticals") (collectively, "Watson"), allege as follows:

NATURE OF THE ACTION

1. This is an action for infringement of United States Patent No. 5,914,131 (the "'131 patent"). This action arises out of Watson's filing of an Abbreviated New Drug

Application ("ANDA") seeking approval to sell generic copies of Plaintiffs' highly successful EXALGO® 32 mg product prior to the expiration of the '131 patent.

<u>THE PARTIES</u>

2. Plaintiff Mallinckrodt Inc. is a Delaware corporation having its principal place of business at 675 McDonnell Boulevard, Hazelwood, Missouri 63042.

3. Plaintiff Mallinckrodt LLC is a Delaware limited liability company having its principal place of business at 675 McDonnell Boulevard, Hazelwood, Missouri 63042.

4. On information and belief, Watson Pharmaceuticals is a Nevada corporation having its principal place of business at Morris Corporate Center III, 400 Interpace Parkway, Parsippany, New Jersey 07054.

5. On information and belief, Watson Pharmaceuticals is in the business of, among other things, developing, manufacturing and selling generic copies of branded pharmaceutical products for the U.S. market through various directly or indirectly owned operating subsidiaries, including Watson Laboratories and Watson Pharma.

6. On information and belief, Watson Laboratories is a Florida corporation having places of business at 4955 Orange Drive, Davie, Florida 33314 and Morris Corporate Center III, 400 Interpace Parkway, Parsippany, New Jersey 07054.

7. On information and belief, Watson Laboratories was formerly known as Andrx Pharmaceuticals, Inc. Watson Laboratories is a wholly owned subsidiary of Andrx Corp., a Delaware corporation that is a wholly owned subsidiary of Watson Pharmaceuticals.

8. On information and belief, Watson Laboratories is in the business of, among other things, developing and manufacturing generic copies of branded pharmaceutical products for the U.S. market.

9. On information and belief, Watson Pharma is a Delaware corporation having its principal place of business at Morris Corporate Center III, 400 Interpace Parkway, Parsippany, New Jersey 07054.

10. On information and belief, Watson Pharma is a wholly owned subsidiary of Watson Pharmaceuticals.

11. On information and belief, Watson Pharma is in the business of, among other things, distributing and selling generic copies of branded pharmaceutical products for the U.S. market.

JURISDICTION AND VENUE

12. This Court has jurisdiction over the subject matter of this action pursuant to 28 U.S.C. §§ 1331 and 1338(a).

13. On information and belief, this Court has personal jurisdiction over Watson Pharmaceuticals, Watson Laboratories and Watson Pharma because, *inter alia,* they have committed, aided, abetted, actively induced, contributed to or participated in the commission of a tortious act of patent infringement leading to foreseeable harm and injury to Mallinckrodt, namely, the submission to the U.S. Food and Drug Administration ("FDA") of the ANDA at issue in this case.

14. On information and belief, this Court has personal jurisdiction over Watson Pharmaceuticals, Watson Laboratories and Watson Pharma because, *inter alia,* they have purposely availed themselves of the benefits and protections of New Jersey's laws such that they should reasonably anticipate being haled into court here. On information and belief, Watson Pharmaceuticals, Watson Laboratories and Watson Pharma have had persistent, continuous and systematic contacts with this judicial district, including, *inter alia,* maintaining executive offices

in New Jersey and, either directly or through an agent, deriving substantial revenue from the development, manufacture and/or sale of pharmaceutical products that are sold in New Jersey.

15. On information and belief, Watson Pharmaceuticals, Watson Laboratories and/or Watson Pharma share certain common employees, officers and directors.

16. On information and belief, each of Watson Pharmaceuticals, Watson Laboratories and Watson Pharma operates in whole or in part from a shared location at 400 Interpace Parkway, Parsippany, New Jersey 07054.

17. On information and belief, Watson Pharmaceuticals organizes its operations by division, including at least the Generic, Brand and Distribution divisions, and reports its financial results in its Securities and Exchange Commission ("SEC") filings by reference to these divisions.

18. On information and belief, Watson's Generic division, which develops, manufactures, markets and sells generic copies of branded pharmaceutical products for the U.S. market, relies on the respective coordinated contributions of at least Watson Pharmaceuticals, Watson Laboratories and Watson Pharma.

19. On information and belief, Watson Pharmaceuticals, Watson Laboratories and Watson Pharma are agents of each other and/or operate in concert as integrated parts of Watson's Generic division.

20. On information and belief, Watson Pharmaceuticals has consolidated its activities and financial results, including revenue earned, with, *inter alia,* Watson Laboratories and Watson Pharma in its SEC filings and Annual Report.

21. On information and belief, Watson Pharma, acting as the agent of Watson Pharmaceuticals and/or Watson Laboratories, distributes and sells in New Jersey and elsewhere

in the United States various generic pharmaceutical products that are manufactured by Watson Laboratories or for which Watson Laboratories is the named applicant on approved ANDAs. On information and belief, Watson Pharma and Watson Laboratories are parties to one or more contractual agreements regarding the distribution of such generic pharmaceutical products. On information and belief, such agreements are at less than arm's length.

22. On information and belief, Watson Pharmaceuticals and/or Watson Laboratories earns revenue from the distribution in New Jersey by Watson Pharma of generic pharmaceutical products that are manufactured by Watson Laboratories or for which Watson Laboratories is the named applicant on approved ANDAs.

23. On information and belief, Watson Pharmaceuticals and Watson Pharma participated in, contributed to, aided, abetted and/or induced the submission to the U.S. Food and Drug Administration ("FDA") of ANDA No. 202144, the ANDA at issue in this litigation. For instance, by letter dated September 10, 2012, Watson Laboratories directed Mallinckrodt to send any correspondence or requests for confidential access concerning ANDA No. 202144 to Mr. G. Michael Bryner, who is registered with the U.S. Patent and Trademark Office as an attorney employed by Watson Pharmaceuticals.

24. On information and belief, Watson Pharmaceuticals and Watson Pharma are registered to do business in New Jersey and have appointed an agent for receipt of service of process in New Jersey.

25. Venue is proper in this Court pursuant to 28 U.S.C. §§ 1391(b) and (c) and 1400(b).

BACKGROUND

26. Mallinckrodt LLC owns all rights, title, and interest in and to the ’131 patent (attached as Exhibit A), titled “Hydromorphone Therapy.”

27. Mallinckrodt Inc. has approval from the FDA to market extended release hydromorphone HCL under the name EXALGO®, including EXALGO® 32 mg. extended release tablets.

28. EXALGO® (hydromorphone HCL) is included in the FDA’s list of “Approved Drug Products With Therapeutic Equivalence Evaluations,” also known as the “Orange Book.” Approved drugs may be used as the basis of a later applicant’s ANDA to obtain approval of the ANDA applicant’s drug product under provisions of 21 U.S.C. § 355(j).

29. The FDA’s “Orange Book” also lists patents associated with approved drugs. The ’131 patent is listed in the “Orange Book” in association with EXALGO® (hydromorphone HCL).

30. On information and belief, Watson Laboratories, itself and with the authorization, contribution, participation, assistance or inducement of Watson Pharmaceuticals and Watson Pharma, submitted ANDA No. 202144 to the FDA under § 505(j) of the Federal Food, Drug and Cosmetic Act, 21 U.S.C. § 355(j), seeking approval to engage in the commercial manufacture, use, and sale of Hydromorphone Hydrochloride Extended-Release Tablets, 32 mg (“Watson’s ER Tablets, 32 mg”) as generic versions of the EXALGO® 32 mg extended-release tablets.

31. Upon information and belief, each of Watson Pharmaceuticals, Watson Laboratories and Watson Pharma, acting in concert as part of Watson’s Generic division, will

market and/or distribute Watson's ER Tablets, 32 mg if and when ANDA No. 202144 is approved by the FDA.

32. By letter dated September 10, 2012, which was received by Mallinckrodt on September 11, 2012, Watson Laboratories advised Mallinckrodt that it had submitted ANDA No. 202144 seeking approval to manufacture, use, or sell Watson's ER Tablets, 32 mg prior to the expiration of the '131 patent.

33. The September 10, 2012 letter also advised Mallinckrodt that ANDA No. 202144 included a certification under 21 U.S.C. § 355(j)(2)(vii)(IV) that, in Watson's opinion, the claims of the '131 patent are invalid and/or will not be infringed by the commercial manufacture, use, or sale of Watson's ER Tablets, 32 mg.

34. The September 10, 2012 letter did not contest infringement of claims 44, 45 or 46 of the '131 patent by the commercial manufacture, use, or sale of Watson's ER Tablets, 32 mg.

COUNT I

Patent Infringement: U.S. Patent 5,914,131

35. Plaintiffs repeat and reallege each and every allegation contained in paragraphs 1 through 33 hereof, as if fully set forth herein.

36. 35 U.S.C. § 271(e)(2) provides that the submission of an application under 21 U.S.C. § 355(j) for a drug claimed in a patent or for a drug use claimed in a patent is an act of infringement if the applicant seeks FDA marketing approval effective prior to the expiration of the patent.

37. Watson's submission of ANDA No. 202144 seeking approval to commercially manufacture, use and/or sell Watson's ER Tablets, 32 mg prior to the expiration of

the ’131 patent constitutes an act of infringement of one or more claims of the ’131 patent under 35 U.S.C. § 271(e)(2).

38. The commercial manufacture, use, or sale of Watson’s ER Tablets, 32 mg will additionally infringe one or more claims of the ’131 patent under 35 U.S.C. § 271.

39. Plaintiffs have no adequate remedy at law to redress the infringement by Watson.

40. Watson’s conduct renders this case “exceptional” as described in 35 U.S.C. § 285.

41. Plaintiffs will be irreparably harmed if Watson is not enjoined from infringing the ’131 patent.

PRAYER FOR RELIEF

WHEREFORE, Plaintiffs respectfully request relief and judgment as follows:

(a) a judgment that the ’131 patent is valid and enforceable, and infringed under 35 U.S.C. § 271(e)(2) by Watson’s filing of its ANDA No. 202144 seeking approval for the commercial manufacture, use and sale of Watson’s ER Tablets, 32 mg;

(b) an order that the effective date of the approval of ANDA No. 202144 seeking approval for the commercial manufacture, use and sale of Watson’s ER Tablets, 32 mg be subsequent to the expiration date of the ’131 patent;

(c) an injunction prohibiting Watson from commercially manufacturing, selling or offering for sale, using, or importing hydromorphone extended release tablets, 32 mg. that are claimed or the use of which is claimed in the ’131 patent or otherwise infringing one or more claims of the ’131 patent;

(d) damages and/or other monetary relief pursuant to 35 U.S.C. § 284 in the event of any commercial manufacture, use or sale by Watson of hydromorphone extended release tablets, 32 mg. that fall within, or the use of which falls within, the scope of one or more claims of the ’131 patent;

(e) an award of Plaintiffs’ interest, costs, reasonable attorneys’ fees and such other relief as the Court deems just and proper pursuant to 35 U.S.C. § 271(e)(4) and 35 U.S.C. § 285; and

(f) such other and further relief as the Court may deem just and proper.

CERTIFICATION PURSUANT TO L. CIV.R. 11.2

Plaintiffs, by their undersigned counsel, hereby certify pursuant to L.CIV.R. 11.2 that the matters in controversy are not the subject of any other action pending in any other court or of any pending arbitration or administrative proceeding.

Respectfully submitted,

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October 25, 2012